

SPL R4 Technical Errors eBook

Interpretations & Solutions for
Technical Errors in SPL R4 Documents
Submitted to FDA

Version 1.1

Purpose:

This SPL R4 training eBook is to be utilized by SPL document authors as a reference to determine the source of technical errors in SPL documents submitted to FDA. This is a “living” document. More content will be included as SPL R4 validation procedures are added or refined. Eventually, this eBook will contain an interpretation of every possible technical error which can occur in an SPL R4 document

How to use this eBook

To eliminate some instances of duplicative error message interpretations in this eBook, this document has been organized into sections by subject. Therefore, if you have several types of errors in your submission, in some cases, you may have to refer to different sections of this eBook. For example, document tracking information is to be included in all three SPL R4 types so the error message interpretations relating to document tracking errors have been grouped into a section labeled “Document Tracking Information.” The other errors in your document may be found in another section (e.g. NDC Labeler Code.) However, a few of the error interpretations are repeated in the appropriate sections. The following table has a list of this eBook’s sections that are applicable to each SPL R4 document type:

SPL R4 Document Types		
NDC Labeler Code	Establishment Registration	Content of Labeling/Listing
Document Tracking Information	Document Tracking Information	Document Tracking Information
NDC Labeler Code	Establishment Registration	Content of Labeling (CoL)/Listing
Contact & Address Information	Contact & Address Information	Images
SPL Schema	SPL Schema	SPL Schema
Packaging & Submitting the SPL	Packaging & Submitting the SPL	Packaging & Submitting the SPL

How do you know when you have received an error message?

A second or third acknowledgment indicates that there is an error in your submission. At the time of the publication of this eBook, error messages (second or third acknowledgments) are transmitted within 24 – 48 hours of FDA's receipt of your submission.

Downloading and viewing an error message

If you have received a second or third acknowledgment, you should download the error message for review. For instructions on downloading and viewing SPL R4 error messages transmitted via the FDA OC Gateway, we recommend that you review the SPL training eBook # 10 via this web page: <http://spl-work-group.wikispaces.com/SPL+eBooks++Graphic+Guides>.

Configuring your PC to view an error message

If you are experiencing technical difficulties resulting in your inability to view the error message you have downloaded, we recommend that you follow these steps:

(for Internet Explorer 7.0)

Click the "Tools" menu and select "Internet Options".

Click the "Security" tab.

Click the "Custom level" button.

Scroll down to the "Miscellaneous" section.

Enable the "Access data sources across domains".

Click "OK" to accept the update.

Click "OK" to close the security dialog.

Validating SPL documents prior to submission to FDA

The Pragmatic Validator Lite Tool is a great resource to utilize to detect technical errors in your SPL R4 documents. However, the validator is **NOT** connected to the FDA database and therefore will **NOT** detect **ALL** SPL R4 technical errors. The validator tool is accessible via this hyperlink: <http://www.fda.gov/ForIndustry/DataStandards/ucm155514.htm>.

Need Additional Assistance w/Error Message Interpretation?

If, after you have reviewed the SPL step-by-step instructions, SPL training eBooks (including this eBook), and eCards, you still require additional assistance regarding the interpretation of your error message, you may request help with the interpretation of the error by submitting an e-mail with the core ID of the submission associated with the error message to spl@fda.hhs.gov. Ensure that you are sending the core ID and not the message ID or submission ID. For assistance with locating the core ID, see SPL training eBook # 10 on this web page: <http://spl-work-group.wikispaces.com/SPL+eBooks+--+Graphic+Guides> .

Other SPL training eBooks

There are other SPL R4 training eBooks and eCards that are accessible via this hyperlink: <http://spl-work-group.wikispaces.com/SPL+eBooks+--+Graphic+Guides>.

Technical Term Definitions	
Term	Definition
Core ID	A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
Hyperlink ID	Used to cross reference sections in content of labeling. Allows reader of document to navigate to the cross referenced sections (Not used in
Observation Media ID	Identifier for the image file (doesn't have to be a GUID)
Product data elements	The structured data about your product(s) (e.g. proprietary name, dosage form, route of administration, package description) (Table at the end of the SPL document)
Section ID	GUID which is used to identify a section
SetID	Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UNII	Unique Ingredient Identifier (UNII) is a non- proprietary, free, unique, unambiguous, non semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.
UUID	Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	Integer greater than zero that provides a sequence to the versions of the document.

Document Tracking Information	
The document tracking information is the: document root ID, setID, version number, and document's effective time.	
Error Message	Solution
There is an id	Include a document root ID (GUID)
SPL file name must be the id root followed by ".xml"	Name the file with the document root ID. (Do not use creative names for the file name.) Include “.xml” after the document root ID
There must be an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
Value " is not facet-valid with respect to pattern '[0-9]{1,8} ([0-9]{9,14} [0-9]{14,14}\\. [0-9]+)([+\\-][0-9]{1,4})?' for type 'ts'.	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
The value " of attribute 'value' on element 'effectiveTime' is not valid with respect to its type, 'ts'.	Enter the date in the document's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)
id must be unique across all documents	Change the document root ID (GUID) to a GUID that is not in FDA system.
" is not a valid value of union type 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
The value " of attribute 'root' on element 'id' is not valid with respect to its type, 'uid'.	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in ID field.
id root must be a Globally Unique Identifier (GUID).	Generate an ID for the document using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in (document) ID field.
id does not have an extension.	Do not include an extension for the ID (this is a coding extension)
id does not match any other id in the document.	Use each GUID one time and one time only.
id is unique across all documents	Use each document root ID one time and one time only – do not use the document root ID in subsequent submissions

Document Tracking Information	
The document tracking information is the: document root ID, setID, version number, and document's effective time.	
Error Message	Solution
There is an id	Include a document root ID (GUID)
setId must be a GUID	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.
The value " of attribute 'root' on element 'setId' is not valid with respect to its type, 'uid'.	Generate a setID using a GUID (also known as UUID). GUID generators are available at no cost online or packaged with the SPL Xforms. Enter GUID in setID field.
Value of version number must be a whole number > 0	Enter a version number which is a whole number that is greater than "0"
" is not a valid value for 'integer'.	Use a whole number in the version number field.
The value " of attribute 'value' on element 'versionNumber' is not valid with respect to its type, 'int'.	Use a whole number in the version number field.
Value of version number must be greater than the value of any previously submitted version for the same setId	Increase the document version number by one whole number.

NDC Labeler Code SPL Documents	
Determine the source of the errors in one's NDC Labeler Code SPL document in the list below.	
Error Message	Solution
There is a labeler organization.	Include the labeler's name
There is a name.	Include the labeler's name

NDC Labeler Code SPL Documents	
Determine the source of the errors in one's NDC Labeler Code SPL document in the list below.	
Error Message	Solution
There are two ids (except for an initial labeler code request, which must be submitted with only one id.)	<p>Include your 4- or 5-digit labeler code unless you are requesting a labeler code.</p> <p>Delete the NDC Labeler code field if you do not have a labeler code to enter. If you receive this message from the Pragmatic Data Validator Lite tool, then note that the error includes this statement: "except for an initial labeler code request, which must be submitted with only one id." This means that you do not need to include the labeler code if you are actually requesting a labeler code</p> <p>In this instance, the "id" is the labeler code. (The second "id" is the DUNS Number. The DUNS Number should only be included in the DUNS Number field.)</p>
The id with the root 2.16.840.1.113883.6.69 must not be associated with any other document of type "NDC Labeler Code request" with a different setId	Do not submit the same NDC labeler code in a different SPL which has a different setId.
The set id is not associated with any other id with root 2.16.840.1.113883.6.69	Submit each NDC labeler code in one NDC Labeler Code SPL document. Do not submit the same NDC labeler code in another NDC Labeler Code SPL document with a different setId.
One id has the root 2.16.840.1.113883.6.69 and an extension (except for an initial labeler code request, which should be submitted without this id)	<p>Include the labeler code in the NDC Labeler Code number field unless you are requesting a labeler code.</p> <p>If you are requesting a labeler code then delete the NDC Labeler Code field.</p>
The id extension with the root 2.16.840.1.113883.6.69 has 4 or 5 digits	<p>Enter an already assigned labeler code using 4 or 5 digits.</p> <p>Do not include leading zeros that are not included in the labeler code segment of your 10-digit NDC</p>

NDC Labeler Code SPL Documents	
Determine the source of the errors in one's NDC Labeler Code SPL document in the list below.	
Error Message	Solution
One id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension	The "id" in this instance is the DUNS Number. Enter the DUNS Number in this field. DO NOT include hyphens in the DUNS Number. Ensure that no spaces are entered (with the keyboard space bar) before or after DUNS Number.
There is no id root besides 1.3.6.1.4.1.519.1 and 2.16.840.1.113883.6.69	Do not include any other IDs associated with data other than the DUNS Number and the labeler code in this file.
A labeler code request has no registrant or establishment information	Do not include registrant or establishment information in an NDC Labeler Code SPL document

Establishment Registration SPL	
Error Message	Solution
has one or two id elements	In this instance, the "id elements" are the DUNS Number and FEI number Enter DUNS Number (FEI number may not be assigned yet. If FEI number for establishment has been assigned, enter it in the FEI number field.)
One id has the root 1.3.6.1.4.1.519.1	Enter 9-digit DUNS Number (without hyphens)
The id with the root 1.3.6.1.4.1.519.1 has a 9-digit extension	Enter 9-digit DUNS Number (without hyphens)
There is one name	Enter the name of the registrant (company name for the owner/operator of drug establishments being registered in this file.)

Establishment Registration SPL	
Error Message	Solution
id must not be associated with any other set id for document type “Establishment registration”	DUNS Number for registrant is associated with only one Establishment Registration SPL document’s setID. Include all of the drug establishments owned/operated by registrant in one Establishment Registration SPL document. If you have already submitted to FDA an SPL as a test or official submission, use the setID of that original Establishment Registration SPL document.
There is one contact party	Include the contact information for the registrant. Please review solutions in the “Contact & Address” information section of this document.
The id is not associated with another establishment in the same SPL file.	Do use the same DUNS Number for more than one drug establishment in your file. DUNS Numbers are site-specific Obtain the other location’s DUNS Number from D&B. If D&B will only assign one DUNS Number because the sites are located on the same campus , at the time of the publication of this eBook, you should enter information for one of the drug establishments.
If the document type is “establishment registration”, then there are one or more establishments.	An Establishment Registration with the document type “Establishment Registration” should have information for one or more drug establishments.
The id with the root 1.3.6.1.4.1.519.1 along with the establishment postal code (if any) and country must match the DUNS number, postal code and country in the Dun and Bradstreet database	Ensure that the DUNS Number and address for a drug establishment is correct . Check to be sure that you have added the ISO 3166-1 3-letter country code. Remove any spaces created with keyboard space bar which are located directly before or after country code.
If there is a second id element, then its root is 2.16.840.1.113883.4.82 and the extension is 7 or 10 digits	In this instance, the “id element” is the FEI number. If you have an FEI number enter it. If not, delete the FEI number field. Enter SEVEN- or TEN- digit FEI numbers. If necessary, include leading zeros for older FEI numbers (e.g. 0001444)
There is one name	There is one name for each drug establishment .
Each establishment has an address	Include an address for each drug establishment . (See the solutions for address errors in the “Contact & Address” information section of this document.)

Establishment Registration SPL	
Error Message	Solution
There is one contact party	Include the contact information for the drug establishment (See the solutions for “Contact & Address” information section of this document.)
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add “import” or “united states agent” as a type of operation for an establishment. Include “import” or “united states agent” in the Importer or United States Agent fields – NOT as the type of operation for a drug establishment
There are one or more establishment operation details (performance act definitions).	Include one or more types of operation for each drug establishment
There is no assigned entity other than for US Agent or Import business.	In the US agent and Import fields, only include the “United States Agent” and “Import”
If the country for the establishment is not “USA”, then there is one US agent	Foreign drug establishment should include information (US agent’s company name, DUNS Number, telephone number, and e-mail address) for one US agent.
If the country for the establishment is “USA”, then there is no US agent	Do not include US agent information for drug establishments located in the USA.
There is one id (US agent)	Include a 9-digit DUNS Number (without hyphens) for the US agent.
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (US agent)	Include a 9-digit DUNS Number (without hyphens) for the US agent.
There is one name (US agent)	Include the name (company name) for the US agent.
There are two or more telecom elements	Include the telephone number and e-mail address for the US agent. (see “Contact & Address” information section of this document for solutions)
If the country code for the establishment is not USA, then there may be one or more import businesses.	If the drug establishment is NOT located in the USA then there MAY be one or more importers.
If the country code for the establishment is USA, then there are no import businesses	If the drug establishment is located in the USA then there should NOT be any importers related to this drug establishment.
There is one id (Importer)	Do not include import information for drug establishments located in the USA.

Establishment Registration SPL	
Error Message	Solution
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (Importer)	Include a DUNS Number (without hyphens) for the importer.
There is one name (Importer)	Enter a name for the importer
There are two or more telecom elements	Include the name (company name) for the Importer agent.
The effective time year matches the current year.	Ensure that the year in the effective time field is the same as the current year.
For a “No change notification” (53410-7) or “Out of business notification” (53411-5) an Establishment Registration with the same setId has been previously submitted.	Do not submit a “No Change Notification” or “Out of Business Notification” Establishment Registration SPL document unless you have already used this setId in a previously submitted technically valid Establishment Registration SPL document with the document type “Establishment Registration”
If the document type is “No change notification” or “Out of business notification”, then there is no registrant information.	Do not include registrant information in a “No Change Notification” or “Out of Business Notification” documents. If you are using the SPL Xforms, do not just delete all of the registrant and establishment information from a previously submitted Establishment Registration SPL document. You should use the “SPLForm_Notification.xhtml” Xforms to create “No Change Notification” or “Out of Business Notification” documents.
If the document type is “No change notification” or “Out of business notification”, then there is no establishment information.	Do not include establishment information in a “No Change Notification” or “Out of Business Notification” documents. If you are using the SPL Xforms, do not just delete all of the registrant and establishment information from a previously submitted Establishment Registration SPL document. You should use the “SPLForm_Notification.xhtml” Xforms to create “No Change Notification” or “Out of Business Notification” documents.
If the document type is “Establishment registration”, then there is registrant information.	If the document type is “Establishment Registration,” then include registrant information.
Establishment registration has no labeler information	Do not submit information about the labeler in the Establishment Registration SPL document. Do not include the labeler code in the Establishment Registration SPL document.

Contact & Address	
This section includes some of the contact or address errors in NDC Labeler Code and Establishment Registration SPL	
Error Message	Solution
There is one contact party	Include the information for one contact entity
There is one contact person name	Include the name of one person as the contact person
The contactParty has an addr	The address should be included for the contact person
An address has street address line, city, and country	Include the street address line, city and country for each address
If the country is “USA”, then the contact party has a state and postal code	If the address is in the United States, include a state and postal code in the address
If the country is “USA”, then the postal code is 5 digits with optionally a dash followed by 4 numbers	If the address is in the United States, include a postal code with five digits. After this zip code, you may include a dash followed by four numbers.
Country must be composed of letters only	Enter a three-letter country code (ISO 3166-1) Delete spaces included before or after country code. Link to 3-letter country code list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162567.htm
There are two or more <telecom> elements	Include a telephone number and an e-mail address
One telecom value begins with “tel:” and is a telephone number	Include “tel:” prior to the entering the telephone number
telephone numbers begin with “+”	Enter a “+” prior to entering the telephone number
telephone numbers must be global telephone numbers;	Enter a telephone number using the proper telephone format
telephone numbers contain no letters or spaces;	Enter the correct format for a telephone number Ensure that there are no spaces created with the keyboard space bar which are located before or after the telephone number.
Include hyphens to separate the country code, area codes and subscriber number	Use hyphens to separate the country code, area codes and subscriber number

Contact & Address	
This section includes some of the contact or address errors in NDC Labeler Code and Establishment Registration SPL	
Error Message	Solution
have any extensions separated by “;ext=” (see Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966).	If you include a telephone number extension, separate from telephone number by “;ext=” (see Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966)
One telecom value begins with “mailto:” and encodes an email address.	Enter an e-mail address. Include “mailto:” prior entering the telephone number
'mailto:' is not a valid value for 'anyURI'.	Enter an e-mail address
an email address is of the simple form <username>@<dns-name>	<ul style="list-style-type: none"> - Enter a valid e-mail address - Remove spaces located before or after e-mail address that were created with keyboard space bar.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Document types considered “listing” documents are all but “NDC labeler code request”, “establishment registration”, “no change notification”, and “out of business notification”.	If you are creating a content of labeling/listing file, do not use these document types: ““NDC Labeler Code Request”, “establishment registration”, “no change notification”, and “Out of Business Notification.”
The document body contains two or more sections	Include more than one section in your content of labeling/listing (CoL/listing) document. However, do not include just one “content of labeling” section to “mislead” the validator. Include a content of labeling in the SPL document for each section in your content of labeling.
One section contains the product data elements	Include a section with product data elements (listing data elements)
There is one labeler	Include the name of the owner of the labeler code.
There is one id	In this instance, reference is made to the labeler’s DUNS Number.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
	Should be identical to labeler's DUNS Number that is associated with labeler code (first segment of NDC in this CoL/listing file) submitted in NDC Labeler Code SPL document.
There is one name	Include the name (owner of the labeler code)
First segment matches an NDC Labeler Code associated with the Labeler id.	Ensure that the labeler code and labeler's DUNS Number is identical to the labeler code and labeler's DUNS Number in your NDC Labeler Code SPL document with this labeler code.
The setId is not associated with any top level product with a different NDC Labeler Prefix	The labeler code in a previously submitted CoL/listing SPL document which has the same setId of this CoL/listing SPL document should be identical to the labeler code in this CoL/listing SPL document. (Enter one labeler code per CoL/listing SPL) This validation procedure does not apply to the labeler code of the NDC for products which are described as components of a kit (combination package)
There is 0 to 1 registrant	The registrant is included if they are listing a drug made for a private label distributor. The information includes the name and DUNS Number. Otherwise, this is blank.
If there is a registrant, then there is one id.	If you enter the registrant information, you should include a DUNS Number (9-digit)
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (registrant)	If you enter registrant information, you should include a DUNS Number (9-digit)
If there is a registrant, then there is one name	If you enter registrant information, you should include the registrant's name.
There is no other element besides id, name and establishments.	Do not include any other elements other those for the DUNS Number, name, & drug establishments.
If the marketing status code for any of the products is not "completed," then there are one or more establishments.	If there is at least one drug product described in the listing document which is still marketed then include the information for one or more drug establishments. If all of the products in this CoL/listing SPL are discontinued then you do not have to include the information for any drug establishment in this CoL/listing file.
Each establishment has one id extension	Include the 9-digit DUNS Number (without hyphens) for each drug establishment.
id has the root 1.3.6.1.4.1.519.1 with a 9-digit extension (establishment)	Include the 9-digit DUNS Number (without hyphens) for each drug establishment.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
id not used for other establishments in the file	Do use the same DUNS Number for more than one drug establishment in the same file. DUNS Numbers are site-specific Obtain the other location's DUNS Number from D&B. If D&B will only assign one DUNS Number because the sites are located on the same campus , at the time of the publication of this eBook, you should enter information for one of the drug establishments.
There is one name (establishment)	Include the name of the drug establishment in the name "field."
Establishment ("assignedOrganization") has no other element besides id and name.	Do not include other element about the drug establishment (in this case the "assignedOrganization" element) other those for the DUNS Number and name
There are one or more business operations.	Include one or more business operations (e.g. manufacture) for each drug establishment
The code comes from the business operations list except for C73599 (import) and C73330 (united states agent)	Add a type of operation; however, DO NOT add "import" or "united states agent" as a type of operation for an establishment.
Act definition code matches code for an establishment with same id previously submitted in documents of type "establishment registration"	If the drug establishment included in the establishment data elements section of your CoL/Listing SPL has been electronically registered via an Establishment Registration SPL, the type of operation included for the establishment in your CoL/Listing matches the type of operation in the previously submitted Establishment Registration SPL document.
If there is no product source, then operation of API manufacture (C82401) and manufacture (C43360) are included	If the source NDC Product Code "field" is not populated then drug establishments with the types of operation "API manufacture" and "Manufacture" should be included. Do Not populate the source NDC Product Code field with an NDC Product Code which is identical to the NDC Product Code for this product just to bypass this validation procedure.
Product data element section has an id	In this instance, the "id" identifies a section. Include a GUID as the id for the section.
id root is a GUID and has no extension.	In this instance, the "id" identifies a section. Include a GUID as the id for the section. Do not include an extension.
There is an effective time with at least the precision of day in the format YYYYMMDD	Enter the date in the section's effective time field using the YYYYMMDD format (e.g. Enter 20091221 for December 21, 2009)

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
There is one or more products	Describe one or more products in the product data element section. Each product should its own product data elements section.
There is a product code	Enter an NDC Product Code (An NDC Product Code are the first two segments of the 3-segment, 10-digit NDC Package Code)
Code has two segments separated by a hyphen	Insert a hyphen between the NDC Labeler Code (first segment of 3-segment, 10-digit NDC Package Code) and NDC Product Code (second segment of 3-segment, 10-digit NDC Package Code)
The first segment is numeric.	Ensure that the first segment (NDC Labeler Code) only consists of numbers.
The second segment is alpha-numeric (letters must be upper-case).	The second segment of the “NDC Product Code – first two segments of 3-segment, 10-digit NDC) is alphanumeric (with letters in uppercase if letters are utilized)
Segments follow the pattern of 4-4, 5-4 or 5-3	Follow the pattern assigned if you received a labeler prior to June 1, 2009. Examples of the patterns of an NDC Product Code are: 4-4: 2222-5555, 5-4: 22222-2222, or 5-3: 22222-876) DO NOT use these exact numbers in your SPL document. Use your own labeler code, etc... Labelers with labeler codes assigned after June 1, 2009, can select pattern; however, once pattern is selected and used in an official CoL/Listing SPL submission, it can not be altered.
The first two segments of the NDC Package Code matches the NDC Product Code	The first two segments of the NDC Package Code (3-segment NDC) are identical to the first two segments of the NDC Product Code. (per product data elements table)
Code has the same labeler segment as the NDC Product Code of all other top-level products in this document.	All top-level products (products which are not considered as inner-component of a kit) should have the same labeler segment for the NDC Product Codes.
Code is not associated with another set id except under parts.	The NDC Package Code (3-segment NDC) may only be associated with one CoL/Listing document’s setID except in the case where the 3-segment NDC is included as a component of a kit (combination package).

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Code has the same length as the NDC Product Code of all other top-level products in this document (i.e., all NDC Product Codes have the same consistent length and hence all NDC Package Codes have the same consistent configuration.)	All NDC Product Codes have the same consistent length and hence all NDC Package Codes have the same consistent configuration.
Code has the same length as any other NDC Product Codes of the same labeler (i.e., all NDC Product Codes by the same labeler have the same consistent length and hence all NDC Package Codes have the same consistent configuration.)	All NDC Product Codes by the same labeler have the same consistent length and hence all NDC Package Codes have the same consistent configuration. (You should not change the configuration of your NDC number.)
If the NDC Package Code has been previously submitted, then the package form code and quantity value and unit are the same as in the most recent submission for this NDC code.	The package description associated with the NDC Package Code (3-segment NDC) of the incoming CoL/Listing SPL document should be identical to the package description for this NDC Package Code in the previously submitted CoL/Listing SPL document.
There is only one product element for each product code, i.e., the same product is not described more than once	The same product is not described more than once in the product data elements section.
There is a name	Include a proprietary/brand name.
Name contains no special symbols (e.g., no “®” or “™” etc) and no “USP”	Do not include symbols or “USP” in the proprietary name of the products in the product data elements section. NOTE: Do not include the dosage, route or strength in the proprietary name field in the product data elements section.
There is a generic medicine name	Include a generic (established) name for the product.

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.

Error Message	Solution
Generic medicine name contains no special symbols (e.g., no “®” or “™” etc) and no “USP”	Do not include symbols or “USP” in the generic/established name of the product in the product data elements section. NOTE: Do not include the dosage, route or strength in the generic name field in the product data elements section.
Generic medicine name contains no suffix.	The generic (established) name should not have a suffix field as the proprietary name could have.
Remove additional qualifiers (e.g. dosage form, route of administration, etc...) from product names in the product data elements section.	Remove dosage form, route of administration, etc... from the product name(s) in the product data elements section of the SPL document.
There is a form code	Include a dosage form for the product
If the product has parts, then the form code is C47916	If this is a multi-component product, you should “Kit” as the “dosage form.”
Product source may be specified under a product	An source NDC Product Code may be included (for repackers and relabelers) (for top-level products and products which are components in a kit (combination product))
NDC Product Code for the source is not the same as the NDC Product Code for the product	Do not include the same NDC Product Code in both the NDC Product Code and source NDC Product Code “fields” in the same product data elements section.
Ingredients may be specified for products and parts	Include ingredients for the products (this also applies to products which are components of a kit)
If the product has parts, then the active ingredients are under parts	If this product is a combination product (kit) then the active ingredients are included in each in product component sections of the kit
There is a strength with a numerator and denominator	For the active ingredient, include a strength and a denominator (e.g. 5 mg in 1 mL or 25 mg in 1 l) (strength is expressed as a ratio.)
Numerator and denominator have a value greater than zero and a unit	The values (numerical amounts in the strength ratio) should be greater than zero. A unit should also be included for both the numerator and denominator for the strength ratio.

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the document type is for 'bulk ingredient' (53409-9), then numerator and denominator are the same.	The numerator and denominator strength for active ingredient in a bulk ingredient listing document should be identical (e.g. 1 kg in 1 kg).
There is no ingredient other than active ingredient (having class code ACTIM, ACTIR, ACTIB), and inactive ingredient (having class code IACT).	There can be no other ingredient classes other than those for the active ingredient, reference drug ingredient, active moiety or inactive ingredients.
If the document type is for 'bulk ingredient' (53409-9), then there is one and only one active ingredient.	In a bulk ingredient (API) listing SPL document, enter one and only one active ingredient.
If the product has no parts and is not a part, then there are one or more active ingredients.	If this is not a combination product (kit), then you should include one or more active ingredients in the product data elements section.
There is an ingredient code	Include an ingredient code
Name matches the code	Use the preferred name and UNII in the UNII list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
There are one or two active moieties	Include one or two active moieties for the active ingredient(s).
There is an active moiety code	Include the UNII for the active moiety
Active moiety name matches the code	Ensure that the active moiety code matches the corresponding preferred term
There is an active moiety name for each active moiety	For each active moiety include the preferred name for that active moiety. Use the preferred name and UNII in the UNII list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Active moiety name does not include any of the names in the Active moiety validation (counter ion) list except if the word appears by itself optionally followed by “cation” or “anion” or “ion”.	Do not include names in the active moiety counter-ion list (labeled “counter-ion validation” located in the Additional Validation Files located on this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm unless word appears by itself optionally followed by “cation” or “anion” or “ion”.
If the class code is ACTIR, then there is an asEquivalentSubstance element with a defining substance	If the basis of strength is a reference drug then there should a name and code which represents the reference drug’s term and UNII.
If the class code is not ACTIR, then there is no asEquivalentSubstance element	If the basis of strength is NOT a reference drug then do not use the reference drug “field”
There is a reference ingredient code	Include a reference ingredient code (UNII)
There is a name (reference drug)	Include the name for the reference drug ingredient
The name matches the code	Add the UNII for the reference drug ingredient
There are zero to many inactive ingredients.	Include or do not include the inactive ingredients in the product data elements section.
There is a strength with a numerator and denominator (inactive ingredient)	For the inactive ingredient, include a strength and a denominator (e.g. 5 mg in 1 mL or 25 mg in 1 L) (strength is expressed as a ratio.)
Numerator and denominator have a value greater than zero and a unit (inactive ingredient)	The values (numerical amounts for the strength in the strength ratio) should be greater than zero. A unit should also be included for both the numerator and denominator for the strength ratio.
If the product has parts, then the inactive ingredients are under parts	If the combination products have inactive ingredients, include the names of the inactive ingredients in the product data element section for the component.
Unit comes from the UCUM units of measures list (strength of ingredients)	Units of measure (UCUM - Unified Codes for Units of Measure) should come from the UCUM list http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm168397.htm
There is an ingredient code	Include an ingredient code

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Name matches the code (inactive ingredients)	Use the preferred name and UNII in the UNII list: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162523.htm If UNII is not included in UNII list then request UNII via e-mail to spl@fda.hhs.gov
Unit comes from the UCUM units of measures list (strength of ingredients)	Units of measure (UCUM - Unified Codes for Units of Measure) should come from the UCUM list http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm168397.htm
If the products has parts, then the form code is C47916	If you are describing a combination product then use “kit” as the dosage form.
If the NDC Product Code was previously submitted, then the product and generic name, source NDC Product Code, active ingredient UNII, dosage form, active ingredient strength, product characteristics of size, shape, color and imprint code must be the same as in the most recent submission for this NDC code.	- The values of the data elements listed in the table cell horizontally adjacent to this cell should match those of the previous SPL for the product(s). - If aforementioned values differ from those in an SPL R3 document then request a “manual override.” - If request is not granted, you will be contacted via e-mail. - If request is granted you will NOT be notified.
There is one marketing category for each product and product part	Include a marketing category for each product (single component product) and each component of a combination product.
Code comes from the <i>Marketing category</i> list	Select a code from the marketing category list (list of acceptable marketing category codes)
If the code is C73583 (ANADA), then the id extension has the prefix “ANADA”	If the marketing category is “ANADA” then application number should be preceded with “ANADA”.
If the code is C73584 (ANDA), then the id extension has the prefix “ANDA” followed by 6 digits	If the marketing category is “ANDA” then the 6-digit application number is preceded by “ANDA”
If the code is C73585 (BLA), then the id extension has the prefix “BLA” followed by 6 digits	If the marketing category is “BLA” then the 6-digit application number is preceded by “BLA”.

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the code is C73593 (NADA) or C73588 (Conditional NADA), then the id extension has the prefix “NADA”	If the marketing category is “NADA” or “Conditional NADA” then the 6-digit application number is preceded by “NADA”.
If the code is C73594 (NDA) or C73605 (NDA authorized generic), then the id extension has the prefix “NDA” followed by 6 digits	If the marketing category is “NDA” or “NDA authorized generic” then the 6-digit application number is preceded by “NDA”
If the code is C75302 (IND), then the id extension has the prefix “IND” followed by 6 digits	If the marketing category is “IND” then the 6-digit application number is preceded by “IND”.
If the code is C73603 (OTC monograph final) or C73604 (OTC monograph not final), then the id extension must match a code in the OTC validation list.	If the marketing category is “OTC monograph final” or “OTC monograph not final” then the regulatory citation must match a code in the OTC validation list. The OTC validation list (otcval.xml) is located in the Additional Validation Files accessible via this web page: http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm
If the code is C80438 (Exempt device), then the id extension consists of 3 letters	If the marketing category is “Exempt device” then the product identifier consists of three letters.
If the code is C80440 (Humanitarian Device Exemption), then the id extension has a prefix “H” followed by 6 digits	If the marketing category is “Humanitarian Device Exemption” then the 6-digit application number is preceded by “H”.
If the code is C80441 (Premarket Application), then the id extension has a prefix “P” or “BP” followed by 6 digits	If the marketing category is “Premarket Application” then the 6-digit application number is preceded by a “P” or “BP”.
If the code is C80442 (Premarket Notification), then the id extension has a prefix “K” or “BK” followed by 6 digits.	If the marketing category is “Premarket Notification” then the 6-digit application number is preceded by “K” or “BK”.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the code is C80438 (Exempt device), C80440 (Humanitarian Device Exemption), C80441 (Premarket Application), or C80442 (Premarket Notification), then there is at least one part.	If the marketing category is “Exempt Device,” “Humanitarian Device Exemption,” “Premarket Application,” or “Premarket Notification” then the product should be a combination product (kit)
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there must be no id.	<p>If the marketing code is not ANADA, ANDA, BLA, Conditional NADA, NADA, NDA, OTC monograph final, OTC monograph not final, NDA authorized generic, IND, Exempt device, Humanitarian Device Exemption, Premarket application or Premarket Notification, then remove the application or citation number or application and citation number code system.</p> <p>Delete the empty application or citation number field. You may have to request to have the empty ID element removed if you still receive error after following above steps. Or you can delete all of the product information to re-enter.</p>
If the marketing category code is not C73626 (bulk ingredient) or C73613 (unapproved medical gas), then there must be at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	<p>With the exception of bulk ingredient and medical gas product SPL documents, include each section of the content of labeling (package insert or drug facts) in each appropriate SPL content of labeling section.</p> <p>Use the appropriate section header for each section. Add a section GUID, title, etc...</p> <p>This means that all other drug products should have a content of labeling sections.</p> <p>DO NOT include an image of the content of labeling. Enter the text or table from the package insert or drug facts in the appropriate sections SPL content of labeling.</p>
If the code is C73603 or C73604, then the id root must be 2.16.840.1.113883.3.149	<p>If the marketing category is OTC monograph final or OTC monograph not final, then choose “Regulatory Citation” as the “Application or citation number code system.”</p> <p>Include a monograph citation number using the correct format (e.g. “part352”)</p> <p>OTC citations are in the otcval.xml file located in the Additional Validation Files located on this web page:</p> <p>http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm169455.htm</p>

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.

Error Message	Solution
If the code is C73583, C73584, C73585, C73588, C73593, C73594, C73605, C75302, C80438, C80440, C80441, or C80442, then the id root is 2.16.840.1.113883.3.150.	If the marketing category is ANADA, ANDA, BLA, Conditional NADA, NADA, NDA, NDA authorized generic, Exempt device, Humanitarian Device Exemption, IND, Premarket Application, or Premarket Notification, then choose “Application” as the “Application or citation number code system.” Enter a six-digit application number preceded by the marketing category prefix (e.g. NDA013444)
If the code is not C73583, C73584, C73585, C73588, C73593, C73594, C73603, C73604, C73605, C75302, C80438, C80440, C80441 or C80442 then there is no id.	If the marketing category is bulk ingredient, medical gas, export only, unapproved drug other, unapproved homeopathic, or unapproved medical gas DO NOT enter an application number and DO NOT include an “application or citation number code system.”
If the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C), then the marketing category is: C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), C73614 (unapproved homeopathic), C73613 (unapproved medical gas) or C73627 (unapproved drug other).	If the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C, then the marketing category is: ANADA, Conditional NADA, NADA, unapproved homeopathic, unapproved medical gas, or unapproved drug other.

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.

Error Message	Solution
If the marketing category is C73583 (ANADA), C73588 (Conditional NADA), C73593 (NADA), then the document type code is: 50577-6 (OTC animal drug), 50576-8 (OTC type A), 50574-3 (OTC type B), 50573-5 (OTC type C), 50578-4 (prescription animal drug), 50575-0 (VFD type A), 50572-7 (VFD type B) or 50571-9 (VFD type C)	If the marketing category is ANADA, Conditional NADA, or NADA, then the document type code is: OTC animal drug, OTC type A, OTC type B, OTC type C, prescription animal drug, VFD type A, VFD type B or VFD type C
If the marketing category is C73626 (bulk ingredient), then the document type is 53409-9 (bulk ingredient)	If the marketing category is bulk ingredient, then the document type is bulk ingredient
If the document type is 53409-9 (bulk ingredient), then the marketing category is C73626	If the document type is bulk ingredient, then the marketing category is bulk ingredient
Status code is “active” or “completed”	Include a marketing status of “active” (on the market) or “completed” (discontinued)
If the status code is active, then there is a low value and no high value	If the product is on the market then include a marketing start date.
If the code is completed, then there is a low and high value	If the product is discontinued then there is a marketing start date and a marketing end date.
The effective time low and high boundary have at least the precision of day in the format YYYYMMDD	The marketing start date and the marketing end date should have this date format: YYYYMMDD.
If there is a high value, then it is not less than the low value.	The marketing end date should be a date that is after the marketing start date.

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Invalid content was found starting with element 'ingredient'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	<p>Delete all of the packaging description information and enter again.</p> <p>To avoid this error, enter all ingredient information and then add package description</p>
Invalid content was found starting with element 'asEquivalentEntity'. One of '{"urn:hl7-org:v3":asContent, "urn:hl7-org:v3":asPartOfAssembly, "urn:hl7-org:v3":part, "urn:hl7-org:v3":instanceOfKind}' is expected.	<p>There is a problem with the source NDC Product Code.</p> <p>Delete the NDC Source Code from the file.</p> <p>Ensure that are using an up to date version of the listing SPL Xforms. If using version 1.02 or older then download a later version and create a completely new SPL document.</p>
Invalid content was found starting with element 'effectiveTime'. One of '{"urn:hl7-org:v3":component}' is expected.	<p>Create a section under content of labeling tab</p> <p>Qualify section from drop-down menu (i.e. Package.Label Principal Display Panel)</p> <p>Create and enter GUID for section (in section ID field)</p> <p>Open “add effective time” field and enter properly formatted data (YYYYMMDD)</p> <p>Open Observation Media fields (“add media”) and complete sections appropriately</p> <p>“Edit” section intended to reference (link to) jpeg image</p> <p>Before referencing image, replace “enter section text here” with appropriate text from label or, if creating a principal display panel section, enter text from principal display panel of carton or container.</p> <p>Ensure that there are no spaces before or after text.</p> <p>Save section and ensure to save document.</p> <p>Repeat above steps for all sections in which images will be referenced.</p>

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
There must not be empty or incomplete elements except, in certain circumstances, code, state, title, text, and time (an id must have a root, a code must have a code system).	Ensure that there are no empty fields
Every top-level product has an “as content” element (optional for parts)	Include a package description for each top-level product (product which is not the inner component of a kit (combination product))
Quantity includes a numerator and denominator	The quantity in the package description includes a numerator and denominator (e.g. 50 tablets (numerator) in 1 box (denominator) or 50 mL (numerator) in 1 vial (denominator))
Remove description of kit package from the parts	Delete the kit package description information from the component level (part) in the product data elements section.
Numerator has a value greater than zero and a unit	The value of the numerator is greater than zero and has a unit.
If the product has parts, then the initial numerator value and unit is “1”	If the product is a combination product (kit) then the initial numerator value and unit is “1”.
Unit of the numerator of the initial package is the same as the units for the denominators of all the strengths	The numerator’s unit of measure for the initial package is the same as the units for the denominator of all of the strengths: (e.g. if the strength is 50 mg in 1 mL , then the unit of presentation for the initial packaging should be “mL” as in 10 mL in a vial. The strength denominator’s unit of measure can be “1” (for a tablet) (e.g. if the strength is 25 mg in 1 1 , packaging description can be 50 tablet in 1 bottle)
Unit of the numerator of an outer package is the same as the unit for the denominator of the quantity of the inner package	The unit of the numerator of outer package should be the same as the unit for the denominator of the quantity of the inner package (e.g. inner level packaging: 50 tablets in 1 bottle /outer level of packaging 1 bottle in 1 box
If the numerator unit is “1” then it has a translation.	Include a translation if the numerator is “1” then use a translation element

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the numerator unit is not “1”, then there is no translation	If the numerator is not “1” then do not include a translation element
Translation code is from the <i>unit of presentation</i> list	The translation code is from the <i>unit of presentation</i> list.
Translation display name matches the translation code	Ensure that the display name for the translation matches the code for the translation.
Translation code agrees with the contained item’s form code. For example, if the form code is “blister pack” (C43168) the translation code is also “blister pack” (C61569) and not “blister”.	Translation code agrees with the contained item’s form code. For example, if the form code is “blister pack” (C43168) the translation code is also “blister pack” (C61569) and not “blister”.
Denominator has value 1 and either no unit or unit “1”	Denominator has value 1 and either no unit or unit “1”
There is a form code and display name	Include a package type and code.
There is a container packaged product code for outermost package except for parts	Include the NDC Package Code (3-segment NDC) for outermost package except for the inner component of a combination product (kit)
Container packaged product code is 10 digits (excluding any hyphens)	Include a ten digit NDC for the package.
NDC Package Code contains three segments divided by hyphens.	Include a 3-segment NDC Package Code the segments divided by hyphens.
The first two segments of the NDC Package Code matches the NDC Product Code	Ensure that the first two segments of the 3-segment NDC Package Code match the NDC Product Code.
Code is not associated with another set id except under parts	NDC Package Code (3-segment NDC) should not be associated with another setID unless it is for the inner component packaging in a combination product (kit)

Content of Labeling & Listing SPL Documents

You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
If the NDC Package Code is mentioned elsewhere in the document, then the package form code and quantity value and unit are the same.	If the NDC Package Code is mentioned elsewhere in the document, then the package form code and quantity value and unit (package description information) are the same.
If the product form code is 'C47916' (KIT), then there must be one or more parts	If "Kit" is the "dosage form" (combination product) then there must be more than one inner component product.
If the product has parts, then at least one part has one or more active ingredients.	If this is a combination product then one of the products should have one or more active ingredients.
Each part has an overall quantity	Include an overall quantity for each product component in a kit (combination product)
If there is an "as content" data element in the part, then the numerator unit is the same as the numerator unit for the "as content" data element (combination product)	If there is packaging then the numerator unit is the same as the numerator unit for the packaging description
If there is no "as content" data element in the part, then the numerator unit is 1	If the inner component product for a combination product does not have packaging then the numerator is "1"
If the dosage form is on the solid oral dosage form list, then there is a color.	Solid oral dosage form products should have a color
If the dosage form is on the solid oral dosage form list, then there is a shape	Solid oral dosage form products should have a shape
There is only one shape element	Solid oral dosage form products should only have one shape characteristic.
If the dosage form is on the solid oral dosage form list, then there is a size	Solid oral dosage form products should have a size
There is a unit and value	Include a unit ("mm") and value (size of product)
Value units is mm	For size include "mm" as the unit (unit of measurement)

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Value is a whole number greater than zero	Size of solid oral dosage form is greater than zero (do not use “0” as the size)
There is only one size element	Only include one size product characteristic per solid oral dosage from product
If the dosage form is on the solid oral dosage form list, then there is scoring	Indicate whether or not a solid oral dosage forms is scored.
The value is 1, 2, 3, 4 or nullFlavor=”OTH”	For scoring the value is “1” (no scoring) “2” (two even pieces) “3” (three even pieces) “4” (four even pieces) “OTH” (other)
There is only one score element	Solid oral dosage form products should each have one score characteristic.
Value has only letters and numbers separated by semicolon without spaces	Solid oral dosage form with an imprint code should have an imprint code that only consists of letters and numbers separated by semi-colon(s) without spaces.
There is only one imprint code element	Each solid oral dosage form should have only one imprint code characteristic.
The code list for the “contains” characteristic is pending	At this time of the publication of this eBook, do not use the “contains” characteristic.
There is one or more “consumed in” substance administration or the product is a top-level product whose form code is C47916.	Include one or more routes of administration unless the top level product is a kit (combination product)
If the document type is for ‘bulk ingredient’ (53409-9), then route code is “not applicable”.	If listing a bulk ingredient then the route of administration should be “Not Applicable” Include “Not Applicable” as the route of administration.
Image file obtained from FDA has the file name assigned by FDA.	Do not use the SPL Product Image characteristic at this time.
Missing or insufficient content of labeling	DO NOT submit content of labeling as a jpeg. Add the text, tables and figures from the package insert or drug facts to each appropriate section of the SPL content of labeling. Include the content of labeling
Each section has zero to many subsections	Each section can have zero to many subsections.
Each section and subsection has an id root and no extension	Include a GUID for each section and subsection

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
Each section and subsection has a code	Each section and subsection should have the appropriate section heading and corresponding code for that section heading.
Each section has an effective time with at least the precision of day in the format YYYYMMDD.	Include an effective time for each section. The effective time should have a date format of YYYYMMDD.
There is a section with the code 51945-4 (principal display panel) with a jpg file (carton/container label).	Include each representative sample of a carton/container label in a major SPL section with section heading "Package.Label Principal Display Panel. (one carton/container label image per section)
There are no figures in the title for a section or subsection.	Do not include figures in title for section or subsection.
There may be excerpts.	There may be highlights text sections for labeling in the Physician's Labeling Rule format.
Excerpts occur only in sections with the following codes: 34066-1 (Boxed Warning), 43683-2 (Recent Major Changes), 34067-9 (Indications and Usage), 34068-7 (Dosage and Administration), 43678-2 (Dosage Forms and Strengths), 34070-3 (Contraindications), 43685-7 (Warnings and Precautions), 34084-4 (Adverse Reactions), 34073-7 (Drug Interactions), 43684-0 (Use in Specific Populations), 49489-8 (Microbiology)	Include highlights text ONLY in these sections: Boxed Warning, Recent Major Changes, Indications and Usage, Dosage and Administration, Dosage Forms and Strengths, Contraindications, Warnings and Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations, or Microbiology.
If there is an excerpt, then it only has highlight text.	Include only highlights text in the excerpt

Content of Labeling & Listing SPL Documents	
You have the right section if you have received errors in your content of labeling/listing SPL document.	
Error Message	Solution
An excerpt in the adverse reactions section (34084-4) includes the statement: "to report suspected adverse reactions" and "1-800-FDA-1088" (different telephone number for documents of type 53404-0 – “Vaccine Label”).	The highlights text of the adverse reactions section includes the statement "to report suspected adverse reactions" and "1-800-FDA-1088" Use a different telephone number for documents of type “Vaccine Label”.
If there are highlights excerpts, then the title for the SPL file includes the text string (without the quotation marks): “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”	If there is highlights text then the SPL document title should include the following text string without quotation marks: “These highlights do not include all the information needed to use” “see full prescribing information for” and “Initial U.S. Approval”
Section for Medication Guide (42231-1) and Patient Package Insert (42230-3) is not a subsection.	Do not include the medication guide or patient package insert section as a subsection.
If the marketing category code is not C73626 (bulk ingredient) or C73613 (unapproved medical gas), then there is at least one other content of labeling section besides those with the codes 48780-1 and 51945-4.	If the marketing category for the product is NOT bulk ingredient or unapproved medical gas then there should be at least one other content of labeling section besides the Principal Display Panel and SPL Listing Data Elements sections.

Images	
For issues with referencing images, see details below	
Error Message	Solution
Reference value must be the file name for the image	Ensure that you have referenced the image in the appropriate content of labeling section - If you are using the Pragmatic Data Validator Lite tool, zip the image with the SPL document and upload the zip file. HOWEVER, DO NOT send a zip file to FDA. - Ensure that you have placed the image in the folder that has the SPL document.
File is a JPEG and the name has the extension “.jpg”	Image file should be a JPEG and should only have a file extension of “.jpg” (file name should be in lower case letters only)
Image components are referenced at least once in the text of any section.	Reference each image at least once in the text of any section
There is text	Include a text description of the image for the computer screen readers to provide the description of image to the visually impaired.
All image files associated with the SPL document must be actually referenced from that SPL document.	Ensure that all files included in the folder are referenced in the SPL document.
Remove extra jpg extension	Do not include an extra jpg extension such as “.jpg.jpg” Use one instead “.jpg”
Size of image file is less than 1 MB	Reduce the size of each image file to under one megabyte (MB)
Media type is image/jpeg	Media type if image/jpeg
Image reference in text has an image “observationMedia” element with a matching ID in the same document.	Image reference in text has an image “observationMedia” element with a matching ID in the same document. The “ID” is the image ID.

Packaging & Submitting the SPL Document

One will receive these errors if one does not observe the proper procedures for packaging an SPL R4 document for the purpose of registering a drug establishment or listing a drug product.

Error Message	Solution
SPL document not enclosed within a directory (folder). See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Enclose the SPL document in a folder and upload the folder containing the file via the FDA Gateway OC portal. The path name in the Gateway field should end in the folder name, not the SPL file name.
<This submission ci1257520697672.5960@lntap02_te.1.zip is incorrectly packaged, it is a ZIP file, not a directory. See section five of Step-by-Step Instructions for Creating Structured Product Labeling (SPL) Files for eLIST Drug Establishment Registration and Drug Listing.	Remove SPL file and, if applicable, image files from the zip file place in a single folder and resubmit via FDA Gateway OC portal.
Multiple SPL files or Submit one SPL file per folder	Include only one SPL document and, if applicable, associated image files per folder.
Extra folder layers	Send the SPL files and, if applicable, associated image files in a single folder.
A submission must contain only the SPL file whose name ends in '.xml' and associated image files whose names end in '.jpg'.	<p>The file extension of the SPL document should be “.xml” (lower case letters only)</p> <p>The file extension of the JPEG image files should be “.jpg” (lower case letters only)</p> <p>DO NOT insert PDF, Excel or Word documents in the folder with the SPL or image files. DO NOT send PDF, Excel, or Word documents to the FDA OC Gateway portal.</p>

Packaging & Submitting the SPL Document	
One will receive these errors if one does not observe the proper procedures for packaging an SPL R4 document for the purpose of registering a drug establishment or listing a drug product.	
Error Message	Solution
Do not send zip files	DO NOT insert zip files in folder with SPL document. DO NOT send SPL document and, if applicable, associated image files in a zip file. You may zip SPL and image file to test submission via Pragmatic Data Validator Lite tool, but unzip submission prior to sending FDA.
Do not send SPL Xforms	Send the SPL documents, not the SPL Xforms used to create SPL document. You should not send any files which have this file extension: “xhtml” SPL documents have this file extension: “xml”
Do not send short cut file	Do not send the short cut file, send the actual file.

SPL Schema or Coding Errors	
The SPL documents must conform to the SPL schema. Basic schema-related errors are listed below.	
Error Message	Solution
There must not be empty or incomplete elements except, in certain circumstances, code, title, text, and time (an id must have a root, a code must have a code system).	Ensure that you have completed the appropriate fields
The value " of attribute 'code' on element 'formCode' is not valid with respect to its type, 'cs'.	Ensure that you have completed the appropriate fields
Value " with length = '0' is not facet-valid with respect to minLength '1' for type 'st'.	Ensure that you have completed the appropriate fields
The value " of attribute 'displayName' on element 'formCode' is not valid with respect to its type, 'st'.	Ensure that you have completed the appropriate fields

SPL Schema or Coding Errors	
The SPL documents must conform to the SPL schema. Basic schema-related errors are listed below.	
Error Message	Solution
If there is a confidentiality code, then the code is “B” and the codeSystem is “2.16.840.1.113883.5.25”	Add the code “B” and the Object Identifier (OID) “2.16.840.1.113883.5.25” if there is a confidentiality code.
Act definition display name matches code	Ensure that the display name for business operation matches the corresponding concept code for that business operation.
Code system is 2.16.840.1.113883.6.69	Use the code system (2.16.840.1.113883.6.69) for Food and Drug Administration Drug Registration and Listing System
Form code has the code system 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus
Display name matches the code	Ensure that the display name matches the code. There is a code for each term. If you receive this error, the code may not have populated the field correctly or you did not use the correct code.
Class code for active ingredients are ACTIB, ACTIM or ACTIR	For the active ingredients, you can only use the following class codes “ACTIB,” “ACTIM,” or “ACTIR”
Code system is 2.16.840.1.113883.4.9	Use the code system (2.16.840.1.113883.4.9) for Food and Drug Administration Substance Registration System
Code system for the translation code is 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) National Cancer Institute Thesaurus
Display name matches form code	Ensure that the display name matches the code.
Code system for NDC Package Code is 2.16.840.1.113883.6.69	Use the code system (2.16.840.1.113883.6.69) for Food and Drug Administration Drug Registration and Listing System
Code is C53292 and code system is 2.16.840.1.113883.3.26.1.1.	Include the marketing status code and use the code system (2.16.840.1.113883.3.26.1.1) National Cancer Institute Thesaurus
If there is a DEA schedule, then the code system is 2.16.840.1.113883.3.26.1.1	If there is a DEA scheduled then use code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus
The policy element has a class code of ‘DEADrugSchedule’.	If there is a DEA schedule then the class code is DEADrugSchedule.

SPL Schema or Coding Errors	
The SPL documents must conform to the SPL schema. Basic schema-related errors are listed below.	
Error Message	Solution
Value code system is 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus
Display name matches the value code	Ensure that the display name matches the value code
Route code system is 2.16.840.1.113883.3.26.1.1	Use the code system (2.16.840.1.113883.3.26.1.1) for National Cancer Institute Thesaurus